



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

SEP 25 2002

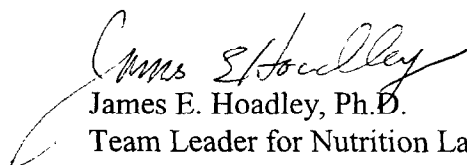
Joan Sabate, MD, DrPH
Professor and Chair,
Department of Nutrition
Professor, Department of Epidemiology
Loma Linda University
School of Public Health
Loma Linda, California 92350

Dear Dr. Sabate:

This letter is in response to your letter dated September 10, 2002, to Michael A. Adams, in which you support the health claim petition submitted by the California Walnut Commission.

We appreciate your interest in the issues raised in the health claim petition. We have forwarded your letter to the Dockets Management Branch (HFA-305) for inclusion in the administrative record under Docket No. 02P-0292. Your letter will be considered by the agency in its deliberations on what action to take on the California Walnut Commission's health claim petition.

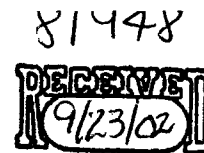
Sincerely,



James E. Hoadley, Ph.D.
Team Leader for Nutrition Labeling and Programs
Division of Nutrition Science and Policy
Office of Nutritional Products, Labeling
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Center for Food Safety
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02P-0292

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September 10, 2002

Michael A. Adams, PhD
Acting Director, Division of Nutrition Science and Policy
Office of Nutritional Products Labeling, & Dietary Supplements
Center for Food Safety and Applied Nutrition
Food and Drug Administration,
Harvey W. Wiley Federal Building
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Attn: Docket #02P-0292

Dear Dr. Adams:

This is a letter in support of the health claim petition that a diet including walnuts can reduce risk of coronary heart disease. There is consistent epidemiological evidence that Americans who choose to eat nuts frequently enjoy a markedly reduced risk for coronary heart disease. Over 10 years ago our research group at Loma Linda University was the first to report that men and women consuming nuts 5 or more times per week had about a 50 % reduction in the risk of heart disease, compared to those eating nuts infrequently (1). This lowering of risk was for developing myocardial infarction as well as dying of coronary heart disease. On our epidemiological study of 34,000 Californians we determined that walnuts were the third most consumed nut, out of the 10 nuts or so available. Three other large prospective cohort studies of diet and health have subsequently reported that frequent nut consumption markedly reduces the risk of coronary heart disease (2-4).

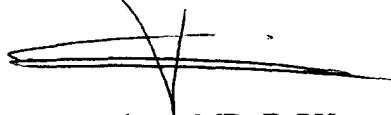
Furthermore, a series of well controlled feeding trials have shown that the incorporation of walnuts to any diet lowers total serum cholesterol and improves the lipoprotein profile (5, 6), important markers for coronary heart disease risk. I conducted the first of such walnut-feeding trials on 18 men comparing the effect of walnuts to a NCEP Step 1 diet (1). The results revealed a reduction of total cholesterol by 12 %, of LDL-cholesterol by 16 % and of the ratio of

LDL/HDL by 12 %, beyond the effects of a NCEP Step 1 diet (7). Similarly, when walnuts were incorporated to a Mediterranean diet and compared to a nut-free cholesterol-lowering Mediterranean diet, total cholesterol, LDL cholesterol and LDL/HDL ratio decreased on the walnut diet by an additional 4 %, 6 % and 8 % respectively, while HDL increased by 3%, beyond the already favorable effect of the Mediterranean diet. Walnuts also improve the lipoprotein profile when incorporated to a low-fat Asian diet (9) and a high-saturated fat western-type diet (10, 11).

Randomized dietary intervention trials have reported markedly reduced risk of recurrent events in cardiac death in patients assigned to a diet including either nuts or being high in α -linolenic acid (12,13). Small to moderate amounts of n-3 fatty acids have been demonstrated to have antiarrhythmic effects and to prevent sudden cardiac death in patient who have had a myocardial infarction (14, 15). Also, dietary intake of α -linolenic acid prevents primary events of coronary heart disease (16). The importance of an adequate intake of α -linolenic acid for good health is such that The Institute of Medicine of the National Academies of Sciences has recently issued dietary reference intakes (DRI) for this essential fatty acid. The DRI for males is 1.6 g/day and for females 1.1 g/day (17). While most nuts are high in monounsaturated fats, walnuts are rich in polyunsaturated fats, including the n-3 α -linolenic acid. Walnuts are one of the few food sources of α -linolenic acid in the American diet. One ounce of walnuts (28 grams) contains 2.5 grams of α -linolenic acid. Thus, half an ounce of walnuts can meet the DRI for this essential nutrient.

In summary, based on the unique nutrient composition of walnuts, and the favorable results from: 1) dietary intervention trials on blood lipids, 2) nutritional epidemiological studies on primary prevention of CHD, and 3) secondary prevention clinical trials, I am convinced there is enough evidence to assert that diets including walnuts on a regular basis reduce the risk of coronary heart disease. Thus, it seems a good public health policy to recommend the inclusion of walnuts to any diet without exceeding energy needs.

Sincerely,



Joan Sabaté, MD, DrPH
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Department of Nutrition
Professor, Department of Epidemiology
Loma Linda University, School of Public Health

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